EXHIBIT S

ISSN 0368-2315

ORGANE DE LA FÉDÉRATION DES GYNÉCOLOGUES ET OBSTÉTRICIENS DE LANGUE FRANÇAISE
ET DU COLLÈGE NATIONAL DES GYNÉCOLOGUES ET OBSTÉTRICIENS FRANÇAIS

JOURNAL DE Gynécologie Obstétrique et biologie de la reproduction

Conceptual advances in the surgical management of genital prolapse

The TVM technique emergence

The TVM Group: J. Berrocal, H. Clavé, M. Cosson, Ph. Debodinance, O. Garbin, B. Jacquetin, C. Rosenthal, D. Salet-Lizée, R. Villet

634 352

Tiré à part

MASSON

November 2004

Publication périodique bi-trimestrielle

J Gynecol Obstet Biol Reprod 2004 ; 33 : 577-587.

Original work

Conceptual advances in the surgical management of genital prolapse

The TVM technique emergence

The TVM Group: J. Berrocal (Rouen), H. Clavé (Nice), M. Cosson (Lille), Ph. Debodinance (Dunkerque), O. Garbin (Strasbourg), B. Jacquetin (Clermont-Ferrand), C. Rosenthal (Brive), D. Salet-Lizée, R. Villet (Paris), all in France.

SUMMARY

Objectives: To describe, in view of its standardization, a new technique of urogenital prolapse repair using a one-piece synthetic mesh.

Material and methods: The history and stages of development in the emergence of the Tension free Vaginal Mesh (TVM) technique are described. The use of a mesh was prompted by the 20-30% recurrence rate associated with conventional repair techniques. Selection of the type of mesh is discussed. Non-absorbable synthetic meshes have shown their interest in visceral surgery. A list of materials along with their respective advantages and inconveniences is reviewed with particular emphasis on tolerance and erosion issues, the latter specific to the vaginal route. The TVM Group selected a one-thread polypropylene mesh, Prolene Soft®, which seemed the most appropriate for the transvaginal approach of prolapse surgical repair. The prosthesis and its design rationale are described. Full details are given on the consecutive stages of the intervention and underlying concepts.

Results: The relevant literature is scarce and there is a lack of methodologically sound studies validating the materials and techniques used. After completion of a first phase of technical refinement and feasibility assessment involving around 300 surgical interventions, the authors initiated a prospective multicenter study. Clinical outcome assessments using feasibility, complications, and efficacy endpoints will be published after twelve months, three years, and five years of follow-up.

Conclusion: Fruitful reasoning led to the development of the TVM technique for the complete surgical repair of genital prolapse, using carefully selected and tested synthetic materiel. Any surgeon can apply this technique after a short period of training.

HISTORY

On June 5, 2000, a group of surgical gynecological specialists interested in pelvic statics, all experienced in the use of synthetic material and willing to participate in thoughtful reasoning to develop a materiel and standardize a technique for the surgical management of urogenital prolapse via the vaginal approach was created in Nice. The group has slightly changed since its creation but still gathers gynecological surgeons working in different settings – university hospital center (3 members), general hospital center (1 member), non-profit private hospital (2 members), and private clinic (3 members) – and in various regions of France. The firm Gynecare France is in charge of the logistic and material coordination of the group.

In the first phase, each surgeon observed the habits and techniques of the others, attending on-site and critically analyzing the interventions performed in the different theaters, which led to the progressive change in the material used and a first attempt at technical standardization.

The work of the group was presented for the first time during a meeting entitled *"Le choix des armes" (the choice of weapons)* held in March 2002 in Marseilles.

Correspondence: Debodinance Philippe, Service de Gynécologie Obstétrique, CH Dunkerque. 43, rue des Pinsons, 59430 Saint-Pol-sur-Mer, France.
Tel.: + 33 (0)3 28 28 58 50 - Fax: + 33 (0)3 28 66 07 15 - E-mail: ph.debodinance@dial.oleane.com

After a period of feasibility assessment of the Tension free Vaginal Mesh (TVM) technique involving approximately 300 surgical interventions, the group initiated a scientific and prospective study with an expected duration of 5 years.

THE USE OF A PROSTHESIS: WHY, AND WHICH ONE?

Why use a mesh?

In their 1987 statement, the National Center for Health Statistics reported that approximately 400,000 yearly operations had been performed for the surgical management of pelvic organ prolapse and urinary incontinence [1]. Since no distinction was made between clinical manifestations, the respective proportions of these 400,000 patients concerned by repair of either anterior or posterior vaginal wall prolapse are unknown. The estimated frequency of vaginal vault prolapse is 5% of all hysterectomies (60,000 cases worldwide). Some estimations suggest that although a certain degree of genital prolapse exists in 50% of women who had children, only 10-20% of these cases are severe enough to provoke symptoms [2].

It has been observed that even when the conventional procedure of anterior and posterior colporraphy was supplemented with other interventions, such as needle urethropexy, repair of bilateral transvaginal and paravaginal lesions, sacrospinous ligament fixation or prespinal repair, enterocele repair or prevention, the recurrence rate still amounted to 20-30% [3-5]. Shull *et al.* [6] reported a cystocele incidence of 30% following vaginal vault suspension, half of cases occurring within the 6 postoperative weeks. They [7] also found a 24% cystocele recurrence rate after vaginal and paravaginal repair. Long-term follow-up data reported by Paraiso *et al.* [8] from 243 patients who had undergone sacrospinous suspension of the vaginal vault showed recurrence rates of 37% and 14% for cystocele and rectocele, respectively.

This clearly emphasizes the clinical need for improvement of the techniques currently used.

Placement of a mesh not only aims at reducing the recurrence rate, but has other objectives such as obtaining a tension-free repair, radically minimizing postoperative pain, reducing difficulty in the passing of feces, and preventing stenosis and dyspareunia. Although meshes – non-absorbable, composite and absorbable – have been used to repair type 3 or 4 prolapse recurrence, authors still do not recommend their use for primary repair because of reported complications [9], including erosion in 10% of cases (with ePTFE), prosthesis ablation in up to 35% and formation of a sinus trajectory in 10% (with Gore-Tex®), and urethral erosion in 4% (with Marlex®).

Some of the causes of prolapse formation have been elucidated [10, 11]: intrinsic deficiency due to tissue collagen weakness, trauma of the pelvic floor and its neural equipment during delivery, hysterectomy, estrogen deficiency and the associated cascade of reactions, aging, and chronic elevation of intra-abdominal pressure (obesity, chronic pulmonary disease, professional efforts and constipation).

Which mesh should be used?

Completely absorbable material (Dexon® and Vicryl®) have no place in the techniques of pelvic anatomical defect repair. It was thought that after being absorbed, they would give way to sufficiently solid fibrous tissue, but this was not confirmed.

Non-absorbable, synthetic meshes have become the gold standard in parietal hernia repair.

The raw material is a sort of paste which is extruded (i.e., passed through a very small hole) to obtain a thread, as if making spaghetti.

Currently manufactured materials are based on polypropylene (Prolene®, Marlex®, Gynemesh®, Atrium®, and Soft Prolene®), or polyethylene-terephtalate, better known as polyester (used to manufacture Mersuture®, Mersilene®, and Parietex® meshes).

Other materials that have been used for many years in other specialties are now rarely used in gynecology (Gore-Tex®) or no longer used alone (Teflon and Silastic).

The linear structure of the thread is important. One-thread and multithread materials are available.

Multi-thread materials are easier to use and more solid. One- and multithread materials are usually knitted.

Indeed, woven material is inappropriate for medical use because it tends to fray and is less supple to use. The mode of thread interlacing determines the characteristics of the knitted material. Medical use of non-woven material seems to be particular to France. This might not be only due to scientific reasons but rather to a quirk in the reimbursement procedures (perhaps there is more to be gained?).

There are a great number of coated products, which have mainly been developed for parietal surgery, to prevent the risk of digestive adherences and associated fistulas (in the case of intra-peritoneal use).

Coating may be:

– biological: cicatrisation stimulants such as glucagon carbohydrate, isolated from oat grains and found in Glucamesh® or collagens coating a surface of the composite Parietex®;

– chemical, with an anti-adherence objective, such as silicone (Europlak® or LIFT® intramesh), Teflon on a Composix® mesh, and polyurethane on a Contex® plaque;

– antiseptic, for example chlorhexidine covering a plaque of Gore-Tex® in Mycro-Mesh®.

It is the comfort of use of a product intended for our work in the operating theater that will appeal to us. For instance, adequate rigidity associated with a good form memory facilitates the endoscopic placing of a mesh. However, the technical characteristics must be known so as to ensure good short- and mean-term tolerance. All marketed materials are sufficiently resistant to replace failing tissue; thin material facilitates tissue colonization and integration compared with 3-dimensional meshes; a low weight reduces inflammatory reactions.

Some surprising examples of weight and thickness of various conventional products are given in *table I*, which shows that the two Surgipro® or two Prolene® forms may not be identical. This is also illustrated by *figure 1*.

Table I Comparative weight and thickness.

	Weight (g/m²)	Thickness (mm)
Surgipro 1 (1994)	84	0.38
Surgipro 2	103.6	0.46
Surgipro 3	97.6	0.59
Prolene 2 (Gynemesh)	96.6	0.64
New Prolene	77	0.53
Gynemesh Soft	42.7	0.42

The concept of interstice must be clearly understood of the risk of infection associated with endovaginal surgery.

Porosity is also a major mesh characteristic. Porosity will promote colonization of the prosthetic tissue "like a lattice by ivy".

Fibroblasts, collagen fibers, and neo-vessels will be incorporated if they can circulate easily between the stitches, provided the pores are large enough.

An estimated *75 µm* threshold is required to obtain adequate tissue integration. In the absence of pores with an adequate size, the prosthesis will be encapsulated instead of being integrated into the surrounding

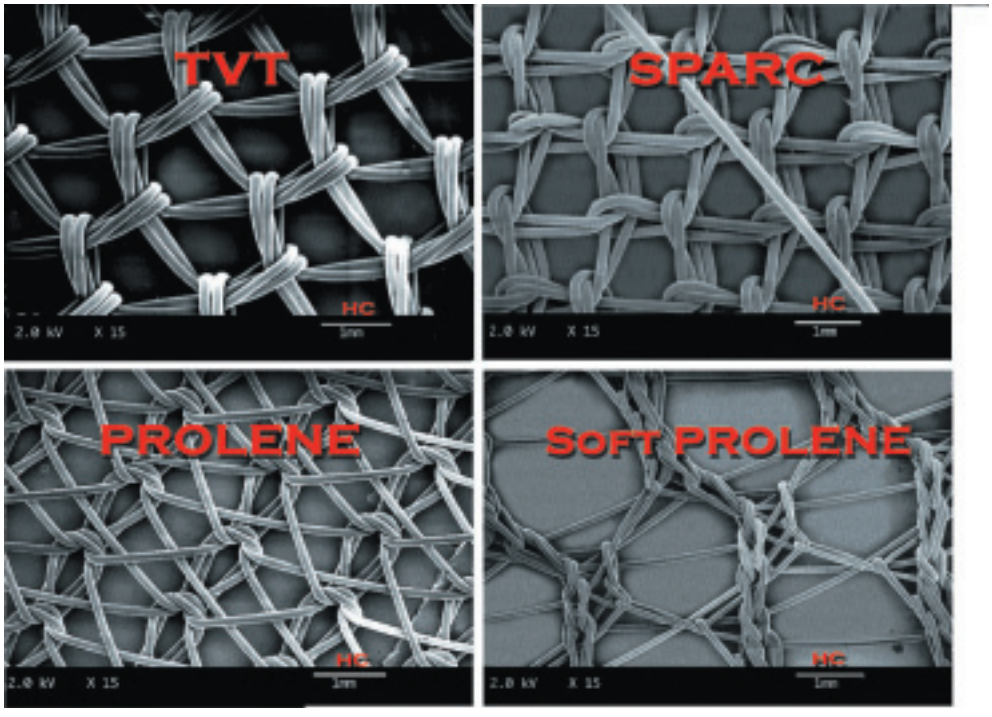

Figure 1 Networking of different prolene meshes.

tissue. Encapsulation is not a sufficient fixation means and is responsible for a high rejection rate. *Table II* provides some examples of porosity.

The retraction phenomenon is impossible to forecast and highly variable. It seems that it would partially depend on both the knitting and the inflammatory reaction. This phenomenon appears enhanced with one-thread materials, which explains some of the postoperative pain originating from meshes fixed by stitches or staples. This phenomenon could be of up to 20%. This implies the placing of meshes with as low a tension as possible.

Erosion is seen with rigid, low-porosity, thick meshes. This complication is deleterious for the organs and may occur many years after the prosthesis has been placed. Primary or secondary erosions of the vagina heal easily with local treatment, or following simple scissor excision of the lesion revealed.

Paradoxically, acute infection is very rare and undoubtedly decapitated by prophylactic antimicrobial therapy. Chronic infection is the real problem associated with the placement of such prostheses.

Glycocalyx is a polysaccharide secreted par bacterial cells, enabling them to adhere to the prosthesis surface and to encapsulate. Protected by glycocalyx, microcolonies develop on the prosthesis surface. Their growth and confluence lead to the formation of a thin and initially superficial coating which will spread until it reaches several millimeters: the biofilm. The biofilm is an assembly of bacterial colonies fixed upon a support and locked up into an encapsulating matrix.

The stable consortium formed is resistant to stress and antimicrobials. Its almost ecological role consists in progressively isolating the support. The support will be rapidly bathing in a sticky, "slime-like" magma. Progressively, without any clear sings of inflammation or infection, the prosthesis will loosen. The micro-organisms involved in most cases are common (*Staphylococcus aureus* or *epidermidis, Pseudomonas aeruginosa*).

Table II Porosity in % and largest space in mm².

Eroplak (non-woven)	17	
Surgipro 2 (multithread)	35	
Surgipro 3 (one-thread)	50	
Prolene 2 (Gynemesh)	50	0.7
Vypro 2	52	4.2
Soft Prolene	64	2.4
Gynemesh Soft	42.7	0.42

When placing a synthetic re-inforcement plaque, the bacterial aggression (mandatory) and the colonization of the mesh by micro-organisms compete. The quicker the colonization, the lesser the space for bacterial proliferation.

To conclude this short review, we will present 2 examples of prices of polypropylene synthetic prostheses. For meshes of the same size, the price may vary from 1 to 11 *(table III)* although there is no evidence that one product is superior to another.

THE TVM TECHNIQUE PROTOCOL

The technique changed during the initial two years of reflexive thinking. Trials were made on cadavers and the application was studied during a feasibility phase.

Description of the prosthesis

Gynemesh Soft® (Ethicon, Sommerville, New Jersey, USA) is a low-weight (42.7 g/m²), thin (0.42 mm) and high-porosity (64%) synthetic, one-thread, polypropylene prosthesis. This mesh is composed of:

– an anterior inter-vesicovaginal prosthesis *(A) (fig. 2)*, inserted as a hammock under the bladder, applied laterally on the arcus tendinus fascia pelvis (ATFP), and retained by two non-secured bilateral transobturator arms: anterior *(a)* at 1-2 cm from the proximal (pre-pelvic) part of the ATFP, posterior *(b)* at 1-2 cm from the distal (pre-spinal) part of the ATFP;

– a posterior inter-recto-vaginal prosthesis *(P) (fig. 2)*, inserted in front of the rectum and applied laterally on the levatores ani, retained by a bilateral lateral arm *(c)* either secured to the median part of the sacrospinous ligament, or crossing the median part of the sacrospinous ligament, interlocked with the perineal tendinous center (PTC) by its transperineal prolongation *(d)*;

Table III Comparative prices.

Knitted	15x15 cm	Woven	61 €
Knitted and coated	15x15 cm	Woven	260 €
Non woven	15x15 cm	Woven	366 €
Non woven coated with PTFE	15x15 cm	Woven	266 €
Knitted and coated (Glucamesh)	15x20 cm	Non-woven	763 €

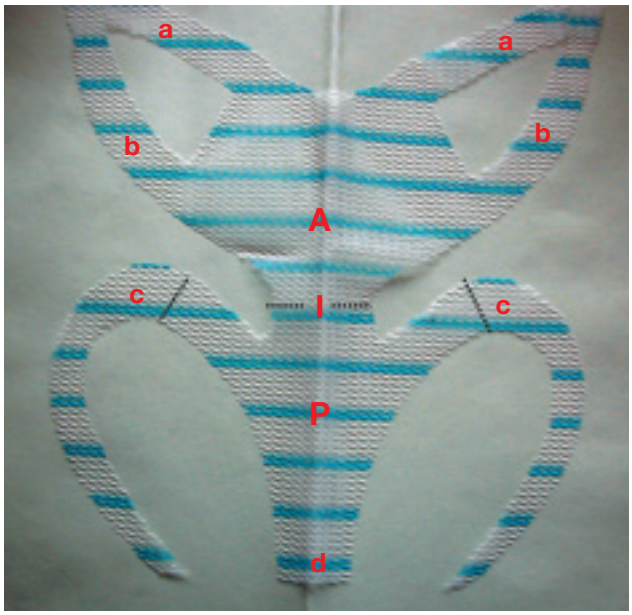

Figure 2 The TVM mesh.

– an intermediate narrowed portion *(I)*: either continuous between *A* and *B* and facing the vaginal apex behind the interlocked uterosacral ligaments, or discontinuous, the free extremities being either left free, anchored to structures such as the uterosacral ligaments, or sutured together to render the prosthesis continuous.

Use of the prosthesis *(fig. 3)*

The prosthesis may be used in a continuous (one-piece) or discontinuous manner (after section of the intermediate portion).

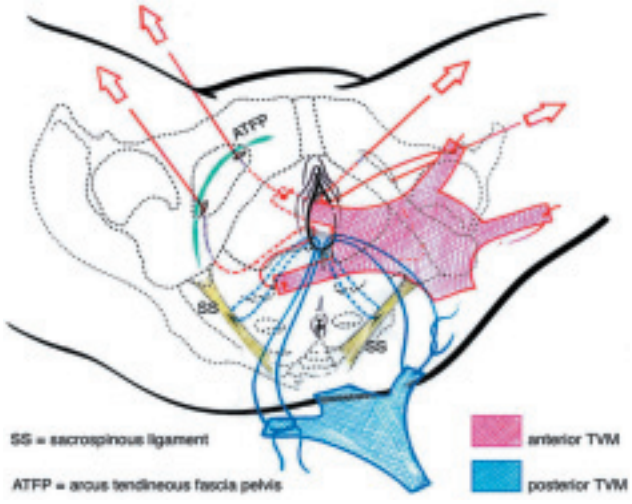

Figure 3 Presentation of meshes before insertion.

Which of the anterior and posterior dissections comes first is aleatory. For one-piece use, a minimum should be to place the 4 transobturator points and the 2 fixed points on or crossing the sacrospinous ligaments (possibly with 2-4 points on the levatores ani and 2 points on the pubic insertion of the pubic-coccygeal ligaments) to install the prosthesis at the last moment.

Intervention principles

Hysterectomy is systematic if not already performed in the patient.

An anterior AND posterior prosthesis must be used (continuous or discontinuous).

Sagittal colpotomy should be avoided on both the anterior and posterior vaginal wall

The suture of the vaginal fundus should be transversal, without colpotomy or limited to simple revival of the edges: in the case of peroperative hysterectomy (transversal incision of the fundus, having crossed or sutured the uterosacral ligaments to part I of the prosthesis) and, in the case of prior hysterectomy, transversal incision of the fundus with eventual excision of the cicatricial tissue and transversal suture.

No levator myorraphy is performed.

Perineal incision is optional: either transversal incision of the vaginal split or diamond-shaped incision of the perineum and vagina; posterior colpotomy should not exceed one third of the vaginal length.

Preoperative preparation

Rectal enema, Betadine shower, shaving or clipping of the pubic and vulvar hair.

Anesthesia

General or locoregional. Routine prophylactic antibiotherapy corresponding to the surgeon's habits. Infiltration of the vaginal wall with a vasoconstrictor solution is permitted.

Patient installation

The patient is in dorsosacral position, with the buttocks slightly protruding from the table, thighs flexed at approximately 90° from the table, legs flexed or stretched out. Widespread painting with Betadine or with a non-iodine antiseptic in allergic patients. An indwelling urinary catheter is installed after cytobacteriological urinanalysis.

Vaginal hysterectomy

Depending upon the usual technique of the operator, annexectomy is optional, and peritonization is performed with extraperitonization of the vascular stumps. The minimum to be kept for future interposition between the prosthesis and the vagina is the following: uterosacral ligaments (mandatory), parametrium (optional), and lateral ligaments (in the absence of hysterectomy) (optional).

Anterior stage (anterior TVM= prosthesis *A*) *(fig. 4)*

The anterior vaginal wall will be maintained using 3 clamps. Dissection of the whole thickness of the anterior vaginal wall (including the Halban's fascia) will be made without colpotomy up to 3 cm from the urinary meatus (to spare the bladder neck), the vaginal wall having been eversed on the operator's finger using the scalpel, and a pad being used to progressively push the bladder back.

In patients with prior hysterectomy, a transversal incision of the vaginal fundus should be made.

Laterally, the bladder is dissected up to the vaginal fornix. It is then usually possible to check that the visceral fascia remains inserted in the parietal fascia. Once the defect is created, the operator's finger easily penetrates into the paravesical fossa. If this is not the case, an orifice will be created within the fascia, usually with a finger, sometimes using scissors closed on insertion and then opened and pulled back. This is the starting point of a wide lateral dissection of the bladder that will expose and permit identification of the whole length of the ATFP, from its pelvic insertion up to its end in the sciatic spine. If it is difficult to palpate or cannot be identified, this theoretical line should be used by the operator to make sure that the prosthesis arms will pass at that level.

At this time, the serous coat of the bladder (it should be remembered that, ideally, Halban's fascia is still on the vaginal wall itself) can be folded with a Monocryl 000 edge-to-edge suture. This may partially reduce a very large cystocele and facilitate placement of the prosthesis.

To identify the transobturator passage, the operator will palpate between his/her thumb and forefinger the obturator membrane in contact with the ischio-pubic branch. The cutaneous incision for the passage of branch *a (fig. 5)* will be made in the area of the anterior-internal part of the obturator orifice, ear the urethral meatus (it should be noted that the passage used for a sub-urethral transobturator prosthesis is located higher, in the widened part of the ischio-pubic branch, corresponding roughly to the clitoris). The cutaneous incision will be made using the scalpel point in the genitocrural fold; it will be limited to 3 mm, which is enough to allow the passage of an eyed needle (Hemmet needle, Deschamp needle, Cousin needle, etc.) in which a caliber 1 guide-thread will be passed. In the first step, the needle will perforate the obturator membrane, which will provoke an easily perceptible projection. The needle guided by the operator's forefinger in the vagina will bypass the ischio-pubic branch and then reappear, after crossing the internal obturator muscle, in the proximal part of the ATFP, i.e. at approximately 1-2 cm from the anterior end of this arch.

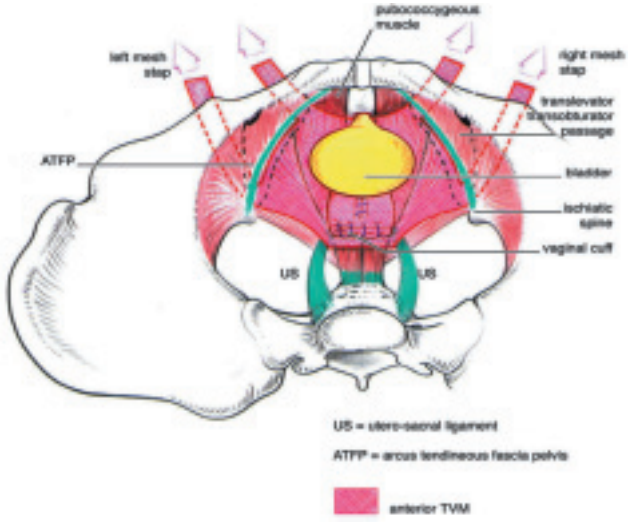

Figure 4 Anterior mesh.

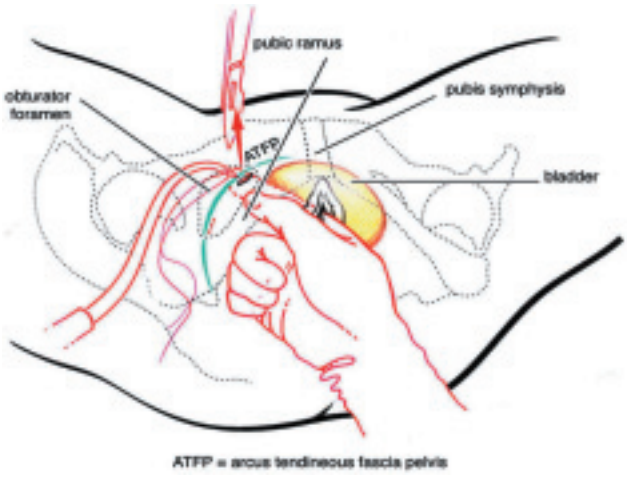

Figure 5 Transobturator insertion of the upper arm.

A second cutaneous incision will be made, still flush with the ischio-pubic branch, approximately 3-4 cm under the previous incision, in the posterior-median part of the obturator orifice. The needle will be equipped as previously but will be sufficiently curved to ensure a trajectory that ends close to the sciatic spine so that it can be easily retrieved in the paravesical fossa. After the obturator membrane has been transfixed, the needle will be directed almost vertically, still controlled by the operator's index finger in the vagina, to progress behind the internal obturator muscle and emerge under (in depth) the ATFP, near its distal insertion, i.e. approximately 1-2 cm from the sciatic spine. Having guided this retro-muscular trajectory, the vaginal forefinger will exert counter-pressure on the levator aponeurosis so that it can be transfixed by the needle. The thread loop in reserve will then be retrieved to enable passage of branch *b (fig. 6)*.

The two transobturator passages will be created on the controlateral sites.

If a discontinuous prosthesis is used, it is possible to place the prosthesis *A*, the ends of arms *a* and *b* being introduced into the thread loops and then pulled back by exerting strong and sustained traction, provided that the operator's finger accompanies the end of the curved prosthesis into the thread loop up to its emergence point to prevent sliding. Thus, the four prosthetic arms emerge from the skin and can be temporarily secured by marked clamps. At this point in time, the prosthesis can be tensed; adjustment is not difficult since the prosthesis surface has been calculated to remain relatively free under the bladder while ensuring lateral contact against the ATFP. Finger control of the adequate lateral application is recommended.

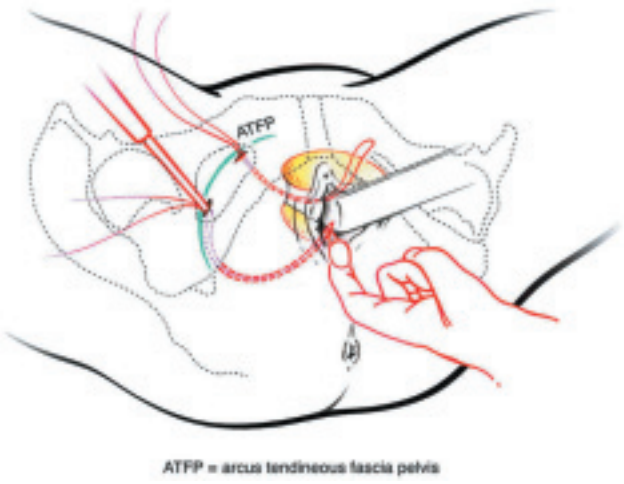

Figure 6 Transobturator insertion of the lower arm.

An optional step consists in securing the prosthesis in front of each insertion of the puborectal muscles in the pubis, making sure that the anterior notch leaves the bladder neck perfectly free. If it is discontinuous, the prosthesis intermediate part *I* may be secured to the uterosacral ligament and/or to the utero-annexial ligament, depending upon the operator's habits. Additional fixations are facultative.

The transversal suture of the vaginal fundus will be made with Monocril 00 type resorbable thread.

The four cutaneous orifices will be closed using either rapid absorption Vicryl 00 or Steristrip.

Middle stage (intermediate portion *I* of the TVM= vaginal apex)

In the case of hysterectomy

With a one-piece prosthesis, the uterosacral ligaments must be fastened in front of the prosthesis at the level of its intermediate portion; this may also be done with parametrium elements (cardinal ligament) and even with the utero-annexial ligaments.

With independent prostheses, part *I* of prosthesis *A* may be left unanchored and pushed under the inferior edge of the bladder or secured either to the parametrium or to the uterosacral ligament. Similarly, part *I* of prosthesis *B* may either be left unanchored and simply pushed toward the Douglas pouch, or secured either to the uterosacral ligaments or to the vaginal angles of the hysterectomy edge.

In the case of prior hysterectomy

If hysterectomy has already been performed: there are usually no identifiable structures. If they are still present, the uterosacral ligaments may be used in the same manner as described in section A, if not, the intermediate part of the continuous prosthesis should not be secured.

The posterior step (posterior TVM= prosthesis *P*) *(fig. 7)*

The perineum will be seized at the muco-cutaneous limit of the split using two clamps forceps separated by 5-6 cm from each other, and a transversal incision will be made. Dissection of the posterior vaginal wall, having placed 2 clips on its edges, will separate the rectum without having to perform a sagittal colpotomy. Good contact with the vagina should be maintained at the start when the cleavage is delicate. Thereafter, dissection will be easy using a finger and a pad and will be performed up to the posterior vagi-

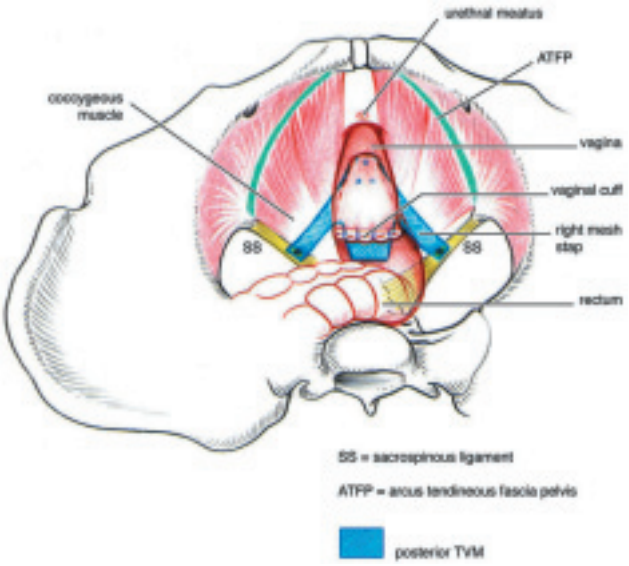

Figure 7 Posterior mesh.

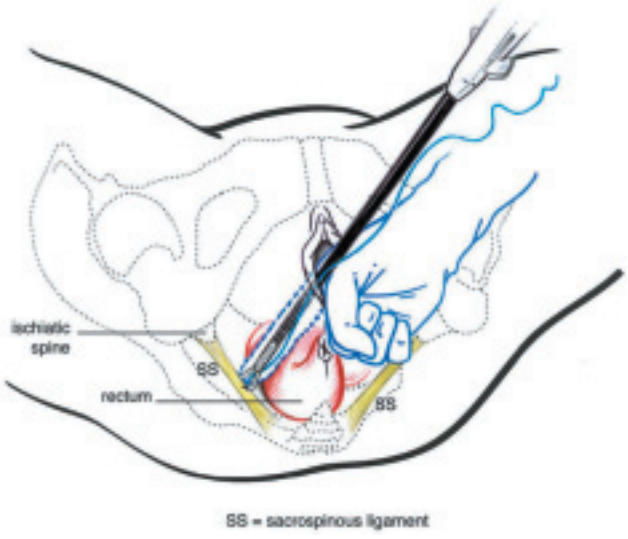

Figure 8 Sacrospinous fixation.

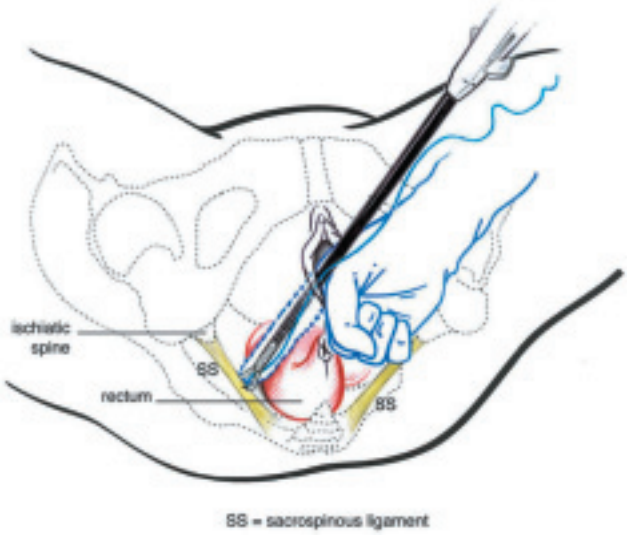

Figure 9 Sacrospinous transfixion.

nal edge of the hysterectomy or up to the fundus incision if the uterus is absent. This dissection should facilitate the introduction of a large so-called "cake server" Breiski pouch to raise the vaginal wall. However, to facilitate exposition, a sagittal incision of less than 1/3 of the length of the posterior vaginal wall is permitted. If the operator has decided to associate perineal repair, a diamond-shaped incision will be made (i.e. a triangle with an inferior vertex in the cutaneous part of the perineum and a vaginal triangle with a tip oriented to join the incision of the posterior vaginal wall). The cutaneous part will be dissected, as well as the inferior part of the vagina, to identify perineal muscles and the perineum tendinous center (PTC).

The rectovaginal dissection will be performed as usual, up to the opening of the pararectal space. The rectum will be lowered to the lateral edge of the sacrum and palpation will enable identification of the sacrospinous ligament from its insertion into the sacrum to its end in the sciatic spine. This technique is identical to that of the Richter's sacrospinofixation.

The pre-rectal fascia can be folded using Monocryl 000. At this stage, the operator has two options:

– direct anchoring *(fig. 8)* to the median part of the sacrospinous ligament (using either a crimped needle, or an instrument equipped with an Endostitch and a non-absorbable thread that will be secured to arm *c* of prosthesis *P*. This thread may be kept in reserve for additional fixation of the vaginal fundus itself;

– creation of a transgluteal trans-sacrospinous passage *(fig. 9)* using a large Cousin-type needle.

If the second option is selected, a cutaneous incision will be made with the scalpel point at 5 cm from the anus, orientated at 45° with regard to the horizontal line passing through the anus, and directed below and outside. This 45° line corresponds roughly to the anus/ischium line. The Cousin needle with an eye in which a provisory caliber 1 thread is passed is introduced into the incision. The needle must proceed behind the levatores ani, under sustained finger control. The rectum should be reclined and maintained distant, either manually, or with a large pouch to prevent any perforation of the rectum. Progression of the

needle will put it in contact with the inferior surface of the sacrospinous ligament. The needle will then transfix the sacrospinous ligament on which counter-pressure should be exerted by the forefinger. When the point of the needle emerges, the thread is pulled back from the needle eye and let on a marked clip. The needle is then pulled back and introduced similarly in the controlateral side. The threads in reserve will permit the arms *c* to be drawn back into the loop that will be made, in the same way as described for the anterior prosthesis. The extremities of the arms *c* are left for subsequent adjustment of the inter-sacrospinous tension, performed at the end of the intervention using rectal palpation. Once this adjustment is made, it is advisable to cut arms *c* as far as possible, while exerting vigorous counter-pressure on the buttocks.

Once arms *c* have been either anchored to the sacrospinous ligament or kept in their transfixing position regarding this ligament, prosthesis *P* is spread out in front of the rectum, with its lateral edges applied on the anterior surface of the levatores ani. To ensure optimal spreading, one or two additional threads may be inserted bilaterally to secure the external edge of the prosthesis to the levatores ani.

The perineal prolongation *d* of prosthesis *P* will be sutured, after adjustment to the length of the PTC, with one or several Vicryl 00 stitches, depending on whether or not perineorraphy is associated. The interest of this is to bury the perineal prolongation and thus prevent or even treat a descending perineum syndrome.

Neither posterior colpectomy, nor simple revival of the edges will be performed if an electrical scalpel has been used for the vaginal section. If the posterior vaginal wall has been opened, simple Monocryl 00 edge-to-edge suture, crossed or reversed, will be used for sagittal closure. Rapid absorption Vicryl 00 will be used for transversal closure of the vaginal split with edge-to-edge suture.

When necessary, gluteal cutaneous incisions will be sutured with a Rapid absorption Vicryl 00 or Steristrip stitch *(fig. 10 and 11)*.

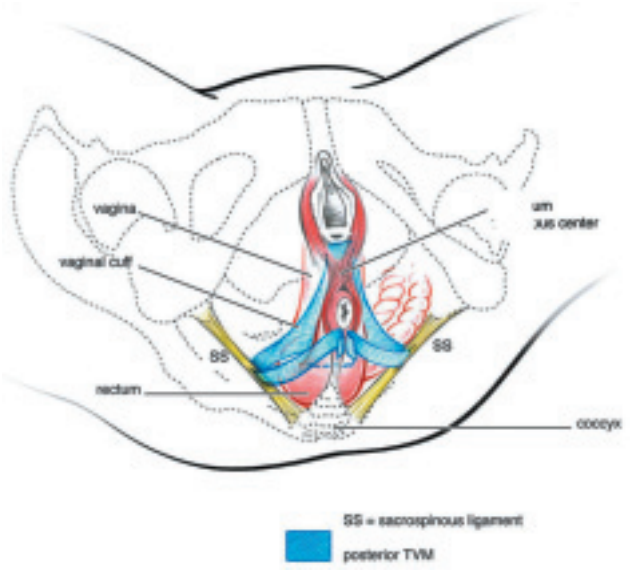

Figure 10 Posterior mesh in place.

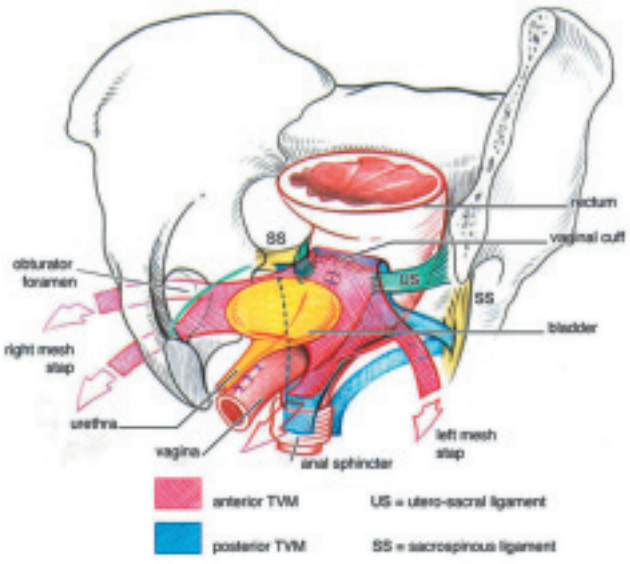

Figure 11 One-piece TVM in place.

Perineal stage (optional)

Any diamond-shaped perineal-vulvar incision will be sutured as usual, using separated Vicryl stitches to cover up the end *d* of prosthesis *P*, thus reducing the vulvar gap, lengthening the ano-vulvar distance and reconstructing the perineal tendinous center. The operator may consider it necessary to use 1-2 low myorraphy stitches to correct a gap, such stitches being placed in front of the prosthesis.

Urinary incontinence management

If a urinary intervention is associated, the urethral incision will not be distinct from the anterior vaginal incision. The nature of urinary intervention is up to the operator, whether by retro-pubic TVT or by sub-urethral support using the transobturator route.

Placing of a vaginal gauze wick

An iodoform gauze wick is left in place until the morning after the intervention, together with 16-type Folley Charriere bladder catheter, which is removed following ablation of the vaginal wick.

Micturition rehabilitation requires systematic control of post-micturition residual urine, until two residues inferior to 100 ml are obtained.

Prevention of postoperative constipation and thromboembolic complications will be systematic.

Patients will be up on Day 1.

DISCUSSION

Our review of the relevant literature has been relatively disappointing. Although a number of articles have dealt with the use of meshes in the surgical management of vaginal prolapse, such articles usually describe non-validated techniques and materials and frequently present retrospective results with follow-up durations rarely exceeding 6 months. For example, among the 751 abstracts presented at the 33rd ICS meeting held in October 2003 in Florence, 20 dealt with the use of various materials for the surgical management of urinary incontinence and 4 with the use of meshes for genital prolapse repair. Among the 269 abstracts presented at the 28th IUGA meeting held in October 2003 in Buenos Aires, 57 dealt with urinary incontinence and 13 with the use of meshes for prolapse repair. Only one reported an 8% erosion rate [12]. De Tayrac *et al.* [13] reported their experience of 48 cystocele repairs using a polypropylene mesh, with a follow-up of 18 months. They noted an 8.3% erosion rate and 97.9% of good results. Eglin *et al.* [14] presented data from 103 cases of cystocele repair with a technique using the obturator route; unfortunately, follow-up was relatively short. These authors reported a 5% erosion rate and a 2% rate of early prolapse recurrence. Julian [15] reported no recurrence in patients treated with a Marlex® mesh versus 16% in controls within a 2-year follow-up, but the erosion rate was 25%. Still in the cystocele repair domain, Migliari *et al.* [16] used a tension-free Prolene® mesh in the management of anterior vaginal prolapse. In their small series of 12 patients followed-up for a mean 20 months, these authors considered that 41% of patients were cured and reported 3 grade 1 cystoceles. Sand *et al.* [17] undertook a prospective randomized study of the Polyglactin 910 mesh. Both groups comprised 80 patients followed up for 52 months. At one year, the recurrence rates in the group without mesh were 31% and 11% for grade 2 and grade 3, respectively. In the mesh group, the corresponding recurrence rates were 22% and 2.7%. The difference was not significant for grade 2 recurrence, and no cases of erosion were reported. These studies have essentially focused on cystocele and very few of them have dealt with the posterior area. Although the relatively easy to treat erosion phenomenon is often reported in those studies, none mentions the much more worrying retraction phenomenon and its after-effects, the symptomatic manifestation of which is dyspareunia.

During the first development stage of our technique, we used a Prolene® standard mesh and we performed longitudinal median colpotomies on the anterior and posterior vaginal walls. Analysis of the first 100 interventions performed by one of the group members showed a 17.5% erosion rate *(table IV)*. Thereafter, we used the Prolene Soft® mesh, stopped performing colpotomies, and only retained the hysterectomy edge and a transversal perineal incision: the erosion rate then dropped to 2.7%. Thus, this drop was probably due to the absence of any scar facing the mesh and the use of Prolene Soft® was probably associated with enhanced improvement in tolerance. This material might have a beneficial effect on retraction events, but this warrants further confirmation.

The TVM group will soon present its retrospective experience of about 400 interventions. A prospective, multicenter clinical trial has just been initiated within the group. Per-protocol clinical outcome assessments using feasibility, complications, and efficacy endpoints will be published after twelve months, three years and five years of follow-up.

Table IV Erosion phenomenon.

TVM		N	Erosion		
With colpotomy	Prolene mesh	56	11	19.6%	11/63 17.5%
	Prolene Soft	7	0	0	
Without colpotomy	Prolene mesh	4	0	0	1/37 2.7%
	Prolene Soft	33	1	3.3%	

CONCLUSION

The TVM technique results from thoughtful reasoning aimed at developing complete surgical repair of genital prolapse. The technique is based on the use of a carefully selected and tested synthetic material. This technique should be reserved to the management of grade 3 and 4 prolapse, possibly as first-line treatment. The intervention lasts no more than 120 minutes and can be performed, following a short training period, by any surgeon interested in pelvic floor surgery and with experience in the vaginal route. The reasoning followed by the TVM group led to the initiation of a study that will analyze the long-term results.

REFERENCES

1. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997; *89*: 501-6.
2. Harris TA, Bent AE. Genital prolapse with and without urinary incontinence. *J Reprod Med* 1990; *35*: 792-8.
3. Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *Am J Obstet Gynecol* 1996; *175*: 1472-5.
4. Morley GW, DeLancey JOL. Sacrospinous ligament fixation for eversion of the vagina. *Am J Obstet Gynecol* 1988; *158*: 872-81.
5. Sze EHM, Micklos JR, Partoll L, Roat TW, Karrat MM. Sacrospinous ligament fixation with transvaginal needle suspension for advanced pelvic organ prolapse and stress incontinence. *Obstet Gynecol* 1997; *89*: 94-6.
6. Shull BL, Capen CV, Riggs MW, Kuehl TJ. Preoperative and postoperative analysis of site-specific pelvic support defects in 81 women treated with sacrospinous ligament suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1992; *166*: 1764-71.
7. Shull BL, Bent SJ, Kuehl TJ. Surgical management of prolapse of the anterior vaginal segment: an analysis of support defects, operative morbidity, and anatomic outcome. *Am J Obstet Gynecol* 1994; *171*: 1429-39.
8. Paraiso MFR, Ballard LA, Walters MD, Lee JC, Mitchinson AR. Pelvic support defects and visceral and sexual function in women treated with sacrospinous suspension and pelvic reconstruction. *Am J Obstet Gynecol* 1996; *17*: 1423-31.
9. Iglesia CB, Fenner DE, Brubaker L. The use of mesh in gynecologic surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 1997; *8*: 105-15.
10. Cespedes RD, Cross CA, McGuire EJ. Pelvic prolapse: diagnosing and treating cystoceles, rectoceles and enteroceles. *Medscape Womens Health* 1998; *3*: 4.
11. Ioozs-Hobson P, Kelvin B, Cardozo L. Management of vaginal vault prolapse. *Br J Obstet Gynaecol* 1998; *105*: 13-7.
12. Achtari CA, O'Reilly B, Schierlitz L, Dwyer PL. Mesh erosion following vaginal repair: is it avoidable? *Int Urogynecol J Pelvic Floor Dysfunct* 2003; *(suppl 1)*: S 65.
13. De Tayrac R, Gervaise A, Fernandez H. Cure de cystocèle voie basse par prothèse sous-vésicale libre. *J Gynecol Obstet Biol Reprod* 2002; *31*: 597-9.
14. Eglin G, Ska JM, Serres X. L. La prothèse sous-vésicale transobturatrice. Tolérance et résultats à court terme d'une série continue de 103 cas. *Gynecol Obstet Fertil* 2003; *31*: 14-9.
15. Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. *Am J Obstet Gynecol* 1996; *175*: 1472-5.
16. Migliari R, De Angelis M, Madedu G, Verdacchi T. Tension-Free vaginal mesh repair for anterior vaginal wall prolapse. *Eur Urol* 2000; *38*: 151-5.
17. Sand P, Koduri S, Lobel RW, Winkler HA, Tomezsko J, Culligan PJ, Goldberg R. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. *Am J Obstet Gynecol* 2001; *184*: 1357-64.


Gynecol
logie
Obstét